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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,615	06/13/2001	Michael W. Johnson	S63.2-9949	7299

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EXAMINER

COZART, JERMIE E

ART UNIT	PAPER NUMBER
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3726

DATE MAILED: 07/01/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,615

Applicant(s)

JOHNSON, MICHAEL W.

Examiner

Jermie Cozart

Art Unit

3726

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-41 is/are pending in the application.
- 4a) Of the above claim(s) 31 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-30 and 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 23, 25, 26, 29, 30, 32, 34, and 35 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Yan (5,843,172).

Yan discloses a method of manufacturing a stent comprising providing a tube having at least two different longitudinally spaced regions of different predetermined physical characteristics (different pore sizes located along the stent), and subsequently cutting the stent from the tube. A first portion of the tube is characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, and is characterized by a second porosity different from the first porosity. Yan also discloses the step of disposing a treatment agent on the stent. The cutting step includes forming a plurality of openings (52) which are elongate. The cutting step also

includes forming a plurality of openings (68) whose widths exceed their lengths. See *column 2, lines 7-14; column 6, lines 61-column 7, line 7; column 7, lines 30-52; and Figures 2, 6, and 8 for further clarification.*

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 23, 24, 27-30, 32, 33, and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter in view of Saunders (5,780,807).

Richter discloses a stent (1) having at least two longitudinally spaced regions (8, 9) and (8', 9') of different predetermined physical characteristics. A first portion (8, 9) of the tube is made from a first metal and a second portion (8', 9') of the tube, longitudinally spaced from the first portion is made from a second metal different from the first metal. Richter discloses a plurality of serpentine segments (Fig. 11) extending about the circumference of the stent, and at least some of the openings being bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment. Richter discloses openings (Fig. 11) which are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment including a first side wall (Fig. 11) and a second side wall (Fig. 11) extending between and connecting the first and second serpentine segments. The first and the second side walls (Fig. 11) are non-parallel to the longitudinal axis of the stent. The first and second

serpentine segments having different physical characteristics. Richter discloses at least some of the openings being bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal. See *column 1, lines 36-54; column 1, line 66 – column 2, line 2; column 4, lines 32 – 40; column 6, lines 5-7, lines 42 – 51, and lines 57-60; column 7, line 63 – column 8, line 22; and Figures 1, 2, and 7-11 for further clarification.*

Richter, however, does not disclose subsequently cutting the stent from a tube, the cutting step including forming a plurality of serpentine segments which extend about the circumference of the stent, the cutting step including forming a plurality of openings which are elongate, the cutting step including forming a plurality of openings whose widths exceed their length, or cutting a plurality of openings in the tube to form a stent.

Saunders`807 discloses cutting a stent (10) from a tube (21), wherein the cutting step including forming a plurality of serpentine segments (30) which extend about the circumference of the stent, forming a plurality of openings (not labeled) which are elongate and whose widths exceed their length, and cutting a plurality of openings in the tube (21) to form a stent (10). See *column 6, line 64 - column 7, line 22, and Figures 4-6 for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to cut the stent of Richter from a tube, wherein the cutting step includes forming the plurality of serpentine segments which extend about the circumference of the stent, forming the plurality of openings which are elongate and whose widths exceed their length, and to cut the plurality of openings in the tube to form the stent, in light of the teachings of Saunders`807, in order to effectively provide a

precision cut stent enabling greater precision reliability, structural integrity and overall quality without burrs or other imperfections.

5. Claims 27, 28, and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan in view of Gray et al.

Yan`172 discloses all of the claimed subject matter, specifically including cutting a metal tube into a desired shape.

Yan`172, however, does not disclose the stent including a plurality of serpentine segments extending about the circumference of the stent, at least some of the openings being bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment, the openings which are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment including a first side wall and a second side wall extending between and connecting the first and second serpentine segments, the first and second side walls being non-parallel to the longitudinal axis of the stent.

Gray discloses a stent including a plurality of serpentine segments (2) extending about the circumference of the stent, at least some of the openings being bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment, the openings which are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment including a first side wall and a second side wall extending between and connecting the first and second serpentine segments, the first and second side walls being non-parallel to the

longitudinal axis of the stent. See column 3, line 18 - column 4, line 64, and Figure 1B for further clarification.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to form the stent of Yan to include a plurality of serpentine segments extending about the circumference of the stent, at least some of the openings being bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment, the openings which are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment including a first side wall and a second side wall extending between and connecting the first and second serpentine segments, the first and second side walls being non-parallel to the longitudinal axis of the stent, in light of the teachings of Gray et al., in order to more effectively form a stent with the desired shape and contour for use during an operation.

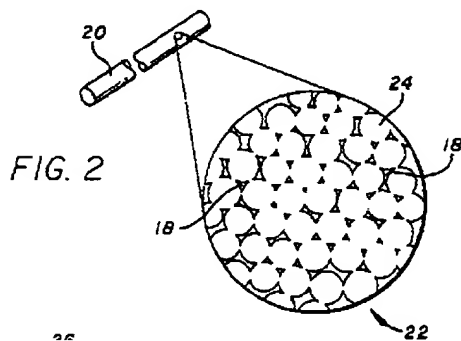
Response to Arguments

6. Applicant's arguments filed 1/8/03 have been fully considered but they are not persuasive.

Applicant repeatedly argues that the Yan reference does not disclose a tube having at least two different longitudinally spaced regions of different predetermined physical properties.

In response, the Examiner maintains that in the Yan reference at Figure 2, there is shown a tube (20) having two different longitudinally spaced regions of different predetermined physical characteristics (i.e. different sized pores (18) spaced longitudinally from one another). As shown in Figure 2 of Yan below, there is a small

pore (18) on the left-hand side of the tube spaced longitudinally from a larger pore (18) located near the right-hand side of the tube. It is therefore clearly evident that Yan discloses a tube (20) having two different longitudinally spaced regions of different predetermined physical characteristics (i.e. different sized pores (18) spaced longitudinally from one another) as already stated previously. The fact that the pores have different sizes indicates that each will have a different porosity. See also column 3, lines 65-67.



Applicant argues that even if there were motivation to cut the Richter stent from a tube, the tube itself would not have different properties until after the cutting and heat treatment.

In response, the Examiner maintains that the stent of Richter can be formed of a particular material having different predetermined physical properties (i.e. different thickness along the length of the stent as well as different metallic properties spaced longitudinally along the stent). The Examiner acknowledges that Richter is silent with respect to whether or not the stent is cut and when the stent is cut. Saunders (5,780,807), however, clearly discloses cutting a stent from a tube into the desired shape apparently after the tube has been formed of the desired material. The

disclosure of Saunders`807 provides the necessary motivation to be combined with Richter, which renders applicant's claimed invention obvious. Each reference is directed to forming a stent, however, Richter does not disclose whether or not the stent is cut from a tube and Saunders`807 provides the supplementary teaching which would lead one having ordinary skill at the time of invention to combine Richter and Saunders`807 to arrive at applicant's claimed invention.

Applicant argues that with Saunders and Richter references, that these references neglect addressing the inventiveness of cutting a stent from a tube which previously been manufactured such that the tube has at least two different longitudinally spaced regions of different predetermined physical characteristics prior to being cut.

In response, the Examiner maintains that Richter clearly discloses forming a stent having at least two different longitudinally spaced regions of different predetermined physical characteristics prior to being cut. Richter, however, does not disclose cutting the stent from a tube. Saunders on the other hand discloses manufacturing a stent from a tube, which as an end result has a complex geometry similar to the stents of Richter. Therefore, the base teachings of Richter when combined with Saunders renders applicant's claimed invention obvious.

Applicant also argues that where different materials are provided, there is no teaching in the combination of references that the different materials of Richter should be combined into a tube and subsequent to that, the tube cut.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, since Richter discloses using different materials in the construction of a stent, then it is apparent that stent is first formed of different materials. It is clearly evident that the stent of Richter is formed of different materials prior to being formed into the desired shape, as there is disclosure definitively stating the contrary. Saunders`807 teaches that a stent can be cut from a tube into a desired shape which thereby provides the necessary to motivation to combine the references rendering applicant's claimed invention obvious.

Conclusion

7. Telephone inquiries regarding the status of applications or other general questions, by persons entitled to the information, should be directed to the group clerical personnel. In as much as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information. M.P.E.P. 203.08. The Group clerical receptionist number is (703) 308-1148.

8. If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers or other general questions should be directed to

Tech Center 3700 Customer Service at (703) 306-5648, or fax (703) 872-9301 or by email to CustomerService3700@uspto.gov.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermie Cozart whose telephone number is 703-305-0126. The examiner can normally be reached on Monday-Thursday, 7:30 am - 6:00 pm.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Greg Vidovich can be reached on 703-308-1513. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Other helpful telephone numbers are listed for applicant's benefit.

Allowed Files & Publication	(703) 308-6789 or (888) 786-0101
Assignment Branch	(703) 308-9723
Certificates of Correction	(703) 305-8309
Drawing Corrections/Draftsman	(703) 305-8404/8335
Petitions/Special Programs	(703) 305-9285
Terminal Disclaimers	(703) 305-8408
PCT Help Desk	(703) 305-3257

If the information desired is not provided above, or a number has been changed, please call the general information help line below.

Information Help line	1-800-786-9199
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Art 3726

JC *[Signature]*
June 30, 2003